



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-411F]

Adjusted Aggregate Production Quotas for Difenoxin, Diphenoxylate (for conversion), and Marijuana

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the adjusted 2015 aggregate production quotas for difenoxin, diphenoxylate (for conversion), and marijuana.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801-971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purposes of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations

(CFR), Chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II each year. The Attorney General has delegated this function to the Administrator of the DEA, 28 CFR 0.100.

Background

The DEA established the initial 2015 aggregate production quotas and assessments for annual need on September 8, 2014 (79 FR 53216). That notice stipulated that, as provided for in 21 CFR 1303.13 and 21 CFR 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment. Based on unanticipated medical, scientific, research, and industrial needs of the United States, the DEA proposed to adjust the established 2015 aggregate production quotas for the schedule I and II controlled substances difenoxin, diphenoxylate (for conversion), and marijuana to be manufactured in the United States in 2015. The notice of proposed adjustment was published in the *Federal Register* on Wednesday, April 8, 2015 (80 FR 18867). All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas on or before May 8, 2015.

Comments Received

Two companies, one institution of higher education, and five private citizens submitted timely comments in response to the proposed adjustment of these three controlled substances. The comments from the institution of higher education and one of the private citizens were in support of the proposed increases for these three controlled substances. The two companies and one private citizen supported the proposed adjustment and requested further increases to the APQs to support research, additional product development efforts, and increases in manufacturing demands. Further comments received from three private citizens were outside the scope of the proposed APQ notice. The DEA appreciates the support for this adjusted 2015 aggregate production quota for difenoxin, diphenoxylate (for conversion), and marijuana, which is intended to provide for the estimated scientific, research, and industrial needs of the United States.

Determination for Adjusting the Aggregate Production Quotas for Difenoxin, Diphenoxylate (for conversion), and Marijuana

In accordance with 21 CFR 1303.13, the DEA has taken into consideration the above comments along with the relevant 2014 year-end inventories, initial 2015 manufacturing quotas, 2015 export requirements, actual and projected 2015 sales, research and product development requirements, and information derived from additional applications for manufacturing quota received since the April 8, 2015 publication of the notice of proposed adjustments to the aggregate production quotas for difenoxin, diphenoxylate (for conversion), and marijuana. Upon consideration of the above, the Acting Administrator has determined to increase the 2015 aggregate production quotas for difenoxin and marijuana beyond that which was previously proposed. Regarding the

aggregate production quota for diphenoxylate (for conversion), the Acting Administrator has determined that the proposed aggregate production quota adjustment for this substance is sufficient to meet the current 2015 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock.

Pursuant to the above, the Acting Administrator hereby establishes the 2015 aggregate production quotas for difenoxin, diphenoxylate (for conversion), and marijuana, expressed in grams of anhydrous acid or base, as follows:

Basic Class—schedule I	Previously Established 2015 Quota (g)	Adjusted 2015 Quota (g)
Difenoxin	50	11,000
Marijuana	125,000	658,000

Basic Class—schedule II	Previously Established 2015 Quota (g)	Adjusted 2015 Quota (g)
Diphenoxylate (for conversion)	0	75,000

Dated: June 11, 2015.

Chuck Rosenberg,
Acting Administrator.

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